8.4 ATTACHMENT IV - 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

DEVICE

Synthes Dual-Opening USS consists of rods, plate/rods, hooks, clamps, screws, nuts and transconnectors. The implants are composed of Titanium or Stainless Steel.

INDICATIONS

When used as a posterior pedicle screw fixation system, the Synthes Small Stature USS and the Dual-Opening USS are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients (including small statue) as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

In addition, the Synthes Small Stature USS and the Dual-Opening USS are intended for treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients (including small stature) and pediatric patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine with removal of the implants after the attainment of a solid fusion. The levels of pedicle screw fixation for these patients are L3-S2.

When used as a posterior non-pedicle screw fixation system in skeletally mature patients (including small stature) and pediatric patients, the Synthes Small Stature USS and the Dual-Opening USS are intended for scoliosis, Schuermann's disease, degenerative disc disease (back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), and fractures of the posterior thoracolumbar spine.

The anterior components of the Synthes Small Stature USS and the Dual-Opening USS when used in skeletally mature patients (including small stature) and pediatric patients are intended for anterolateral screw and/or staple fixation for the correction of anterolateral lordotic deformities for the spine, lumbar scoliosis, pseudoarthrosis, and fracture or dislocation of the thoracolumbar spine (levels T8-L5).

In addition, when used with 3.5/5.0 mm parallel connectors, the Synthes Small Stature USS can be linked to the CerviFix™ System. When used with 5.0/6.0 mm parallel connectors, the Synthes Small Stature USS can be linked to the Universal Spinal System and the Dual-Opening USS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 5 2002

Ms. Vikki Hoffman
Senior Regulatory Affairs Specialist
Synthes Spine
Post Office Box 0548
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K020517
Trade Name: Synthes Dual Opening USS
Regulatory Number: 21 CFR 888.3070, 21 CFR 888.3050
Regulation Name: Pedicle Screw Spinal System, Spinal Interlaminal Fixation Orthosis
Regulatory Class: II
Product Code: MNI, MNH, KWP
Dated: March 22, 2002
Received: March 25, 2002

Dear Ms. Hoffman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Milhern

Celia M. Witten, Ph.D., M.D.
Director
Division of General Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

8.2 ATTACHMENT II – INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K020517

Device Name: **Synthes Dual-Opening USS**

Indications for Use:

When used as a posterior pedicle screw fixation system, the Synthes Small Stature USS and the Dual-Opening USS are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients (including small statue) as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

In addition, the Synthes Small Stature USS and the Dual-Opening USS are intended for treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients (including small stature) and pediatric patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine with removal of the implants after the attainment of a solid fusion. The levels of pedicle screw fixation for these patients are L3-S2.

When used as a posterior non-pedicle screw fixation system in skeletally mature patients (including small stature) and pediatric patients, the Synthes Small Stature USS and the Dual-Opening USS are intended for scoliosis, Schuermann's disease, degenerative disc disease (back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), and fractures of the posterior thoracolumbar spine.

The anterior components of the Synthes Small Stature USS and the Dual-Opening USS when used in skeletally mature patients (including small stature) and pediatric patients are intended for anterolateral screw and/or staple fixation for the correction of anterolateral lordotic deformities for the spine, lumbar scoliosis, pseudoarthrosis, and fracture or dislocation of the thoracolumbar spine (levels T8-L5).

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020517

In addition, when used with 3.5/5.0 mm parallel connectors, the Synthes Small Stature USS can be linked to the CerviFix™ System. When used with 5.0/6.0 mm parallel connectors, the Synthes Small Stature USS can be linked to the Universal Spinal System and the Dual-Opening USS.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use_____
(Per 21 CFR § 801.109)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020517